510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Submitter Information:**

CooperVision, Inc.
711 North Road
Scottsville, NY 14546

Contact Person: Bonnie Tsymbal
Manager, Regulatory Affairs

Telephone: (585) 264-3210

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Date Prepared: February 5th, 2002

2. **Device Name:**

Common Name: Soft (hydrophilic) Contact Lens

Trade/Proprietary Name: Frequency 55 UV (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear

Device Classification: Class II

3. **Predicate Device:**

The predicate devices are the Sauflon 55 UV (methafilcon A) Soft (hydrophilic) Visibility Tinted Contact Lens marketed by Sauflon Pharmaceuticals Ltd. and Frequency 55 with UVAM (methafilcon A) (Sphere, Asphere and Toric) Soft (hydrophilic) contact lenses for daily wear manufactured by Aspect Vision. The predicate devices were cleared under K013649 and K982997 respectively. The devices were selected as the predicate devices based on the material, intended use and design.

4. **Device Description:**

Frequency 55 UV and Frequency 55 UV Aspheric (methafilcon A) soft (hydrophilic) contact lenses are available as spherical lenses. Frequency 55 UV Toric (methafilcon A) soft (hydrophilic) contact lenses are available as astigmatic (toric) lenses. The lens material, methafilcon A, is a random copolymer of hydroxyethylmethacrylate and methacrylic acid. A benzophenone UV absorbing monomer is used to block UV radiation. The average transmittance characteristics are less than 10% in the UVB range of 280 to 315 nm and less than 40% in the UVA range of 315 to 380 nm. The lenses are tinted aqua from edge to edge for visibility purposes with the color additives, C.I. Reactive Blue No. 4 and C.I. Reactive Yellow 86.

Frequency 55 UV, Frequency 55 UV Aspheric and Frequency 55 UV Toric contact lenses are hemispherical shells with the following dimensions:

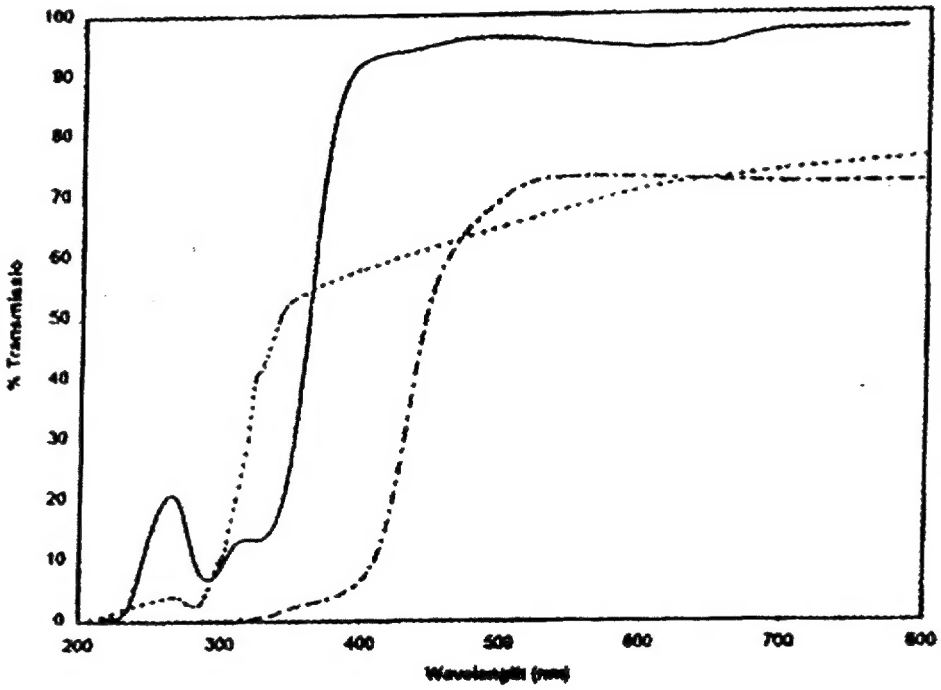
- Diameter: 14.0mm to 15.0mm
- Base Curve: 8.0mm to 9.5mm
- Center Thickness: 0.03mm to 0.60mm (varies with power)
- Spherical Powers: -20.00 to +20.00D
- Cylindrical Powers: plano to –12.00
- Axis: 1° to 180°

The physical/optical properties of the **Frequency 55 UV and Frequency 55 UV Aspheric** and **Frequency 55 UV Toric** contact lenses are:

- Refractive Index: 1.40
- % Transmittance @ 590nm: >90%
- % Transmittance @ 280-315nm: <10%
- %Transmittance 316-380nm <40%
- Water Content; 55%
- Oxygen Permeability: 22.0 x 10^{-11} (cm^2/sec)(ml O^2/ml x mmHg) at 35°C
  Fatt Method for determination of oxygen permeability)

Transmittance Curves

The figure below shows transmittance curves comparing the Frequency 55 UV (methafilcon A) contact lens with visibility tint and UV blocker, against those for a 24 yr. old human cornea and 25 yr. old human crystalline lens.



_____ Data was obtained from measurements taken thru the central 3-5mm portion of a Frequency 55 UV (methafilcon A with UV blocker) soft contact lens with visibility tint and UV blocker. Curve shown is for a –6.75D lens with a center thickness of 0.06 mm which represents the transmittance characteristics of the thinnest version of this UV-absorbing lens to marketed.

..... 24 Year old human cornea *1

_._._._._._ 25 year old crystalline lens *2

N.B.

1. Lerman, S., Radiant Energy and the eye, MacMillan, New York, 1980, p.58, Fig 2-21
2. Waxler, M. Hitchins, V.M., Optical Radiation and Visual Health, CRC Press, Boca Raton, Florida, 1986, p. 10 Fig. 5

5. Indications for Use:

Frequency 55 UV lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

Frequency 55 UV Toric lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who have astigmatism of 12.00 diopters or less.

FREQUENCY 55 LENSES WITH UV ABSORBING MONOMER HELPS PROTECT AGAINST TRANSMISSION OF HARMFUL UV RADIATION TO THE CORNEA AND THE EYE.

Note: Only chemical (not heat) and hydrogen peroxide disinfection systems may be used with Frequency 55 UV lenses.

Frequent/Planned Replacement Wear

When prescribed for Frequent/Planned Replacement Wear, the Frequency 55 UV and Frequency 55 UV Toric lenses are to be cleaned, rinsed and disinfected each time they are removed from the eye and discarded after the recommended wearing period prescribed by the eye care practitioner.

Disposable Wear

When prescribed for Disposable Wear, the wearing time prescribed by the eye care practitioner is for daily wear (single use). Patients should be instructed to discard the lenses at each removal.

6. Substantial Equivalence:

Comparison to Predicate Device

	Frequency 55 UV UV416 (methafilcon A) Soft (hydrophilic) Contact Lens for Daily Wear	Sauflon 55 UV UV416 (methafilcon A) Soft (hydrophilic) Contact Lens for DW **K013649**	Frequency 55 with UVAM (methafilcon A) Soft (hydrophilic) Contact Lens for DW **K982997**
Lens Material	methafilcon A	Methafilcon A	methafilcon A
Material Classification	Group 4 >50% ionic polymer	Equivalent	Equivalent
Indication	Myopia, hyperopia and astigmatism	Myopia and Hyperopia	Myopia, hyperopia and astigmatism
Water Content	55%	55%	55%
Light Transmittance (%) At 590nm UVA region (316-380nm) UVB region (280-315nm)	 94.61 36.00 9.41	 94.61 36.00 9.41	 93.58 4.09 6.00
Dk (35° C)	15.8×10^{-11}	15.8×10^{-11}	14.0×10^{-11}
Powers	+20.00 to –20.00 D	+20.00 to –20.00 D	+20.00 to –20.00 D
Tint	Clear or Aquamarine	Aquamarine	Clear or Aquamarine
Manufacturing Method	Fully Molded	Fully Molded	Fully Molded
Lens Design	Spherical Aspheric Back Surface Toric	Sphere	Spherical Aspheric Back Surface Toric
Packaging	Blister Pack	Blister Pack	Blister Pack

7. Toxicology

The following toxicological tests were performed on Frequency 55 UV lenses:

a) Cytotoxicity Study Using the ISO Agarose Overlay Method

Under the conditions of this study, the test article showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the test. The negative and positive controls performed as anticipated.

b) ISO Ocular Irritation Study in the Rabbit

Under the conditions of this study, the test article extracts would not be considered irritants to the ocular tissue of the rabbit.

c) ISO Acute Systemic Toxicity Study in the Mouse

Under the conditions of this study, there was no mortality or evidence of systemic toxicity from the extracts. Each test article extract met the test requirements.

8. Additional Non-Clinical Testing

a) Leachability Study

Leaching studies were undertaken to demonstrate colorfastness of assessing the acceptability of tinting the Frequency 55 UV lens with CI Reactive Blue and Reactive Yellow 86. This study demonstrates how, after two weeks of extraction at 37°c in saline, undetectable levels of dye (below 1ppm) were observed in the extraction solutions.

b) Determination of Extractables using High Pressure Liquid Chromatography

Under the conditions of this study, the test extracts did no contain residual monomers within the detection limits of the analysis.

9. Conclusions

The Frequency 55 UV (methafilcon A) Soft (hydrophilic) Contact Lens will be manufactured according to specified process controls and an ISO 9001/EN46001 and CGMP quality assurance program currently in place. The established safety profile (preclinical, toxicological, chemical/optical) of the Frequency 55 UV is equivalent to Sauflon 55 UV and Frequency 55 with UVAM.

Being similar with respect to indications for use, materials and comparable physiochemical properties to the predicate devices, this meets the requirements per section 510(k) of the act regarding substantial equivalence and does not raise questions of safety and effectiveness than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 6 2002

CooperVision, Inc.
c/o Ms. Bonnie Tsymbal
Manager, Regulatory Affairs
711 North Road
Scottsville, NY 14546

Re: K020392
Trade/Device Name: Frequency 55 UV (methafilcon A) Soft (hydrophilic)
Regulation Number: 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL
Dated: February 5, 2002
Received: February 6, 2002

Dear Ms. Tsymbal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
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Center for Devices and
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Indication for Use Statement

510(k) Number: K020392

Device Name: Frequency 55 UV
Frequency 55 UV Aspheric
Frequency 55 UV Toric

Indication for Use:

1. **Frequency 55 UV and Frequency 55 UV Aspheric** lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.

2. **Frequency 55 UV Toric** lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who have astigmatism of 12.00 diopters or less.

FREQUENCY 55 LENSES WITH UV ABSORBING MONOMER HELPS PROTECT AGAINST TRANSMISSION OF HARMFUL UV RADIATION TO THE CORNEA AND THE EYE.

Note: Only chemical (not heat) and hydrogen peroxide disinfection systems may be used with Frequency 55 UV lenses.

Frequent/Planned Replacement Wear

When prescribed for Frequent/Planned Replacement Wear, the Frequency 55 UV and Frequency 55 UV Toric lenses are to be cleaned, rinsed and disinfected each time they are removed from the eye and discarded after the recommended wearing period prescribed by the eye care practitioner.

Disposable Wear

When prescribed for Disposable Wear, the wearing time prescribed by the eye care practitioner is for daily wear (single use). Patients should be instructed to discard the lenses at each removal.

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel W. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K020392

JS

Prescription Use X OR Over-The-Counter _____
(Per 21 CFR 801.109)